K040995

MAY 2 5 2004

ANALOGIC®

# 510(k) Summary
# For
# Analogic Corporation
# AN6150 Digital Radiology System

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92

**Submitter's Name and Address:**

Analogic Corporation
8 Centennial Drive
Peabody, MA 01960

**Date this Summary was Prepared:**

April 15, 2004

**Contact Person:**

Donald J Sherratt, Regulatory Affairs Manager
Tel: (978) 977-3000 extension 3049
Fax: (978) 977-6808

**Device Name:**

| | |
|---|---|
| Proprietary or Trade Name: | AN6150 Digital Radiology System |
| Common Name: | Digital Radiology Systems |
| Classification Name: | Digital Radiology Systems and Accessories |

**Predicate Device:**

The legally marketed devices to which equivalence is being claimed are:

The Analogic AN5150 and AN7150 Digital Radiology Systems. These systems were cleared under Premarket Notification K033345.

**Device Description:**

**Intended Use**

The AN6150 is a digital X-ray general radiography system intended for use by qualified/trained doctor or technician and is designed to perform radiographic exposures of the whole body including skull, spinal column, chest, abdomen, extremities and other body parts excluding mammography. Radiographic exposures may be taken with the patient in the sitting, standing, or lying in the prone or supine position.

Images from the AN6150 are available for preview by the doctor / x-ray technician on the operator's workstation within seconds of the x-ray exposure. After acceptance, by the operator the digital (DICOM) images can be stored on electronic media, or exported to a (DICOM/PACS) network, clinical review station or to a film printer.

**Comparison of Technological Characteristics:**

The design of the new AN6150 Digital Radiology System is derived from the design of the Digital Radiology Systems AN5150 and AN7150.

**Voluntary Standards Used in Determination of Substantial Equivalence:**

The design of the AN6150 Digital Radiology System has been thoroughly validated at the unit and system level and meets all elements of its Requirements Specification. This included the following non-clinical tests:

- IEC 60601-1:1988, +A1:1991, +A2:1995, an FDA recognized consensus standard for safety of medical electrical equipment.
- IEC 60601-1-1:
- IEC 60601-1-3:1994, Medical electrical equipment - Part 1: General requirements for safety - 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment
- IEC 60601-2-7:
- IEC 60601-2-28
- IEC 60601-2-32:
- IEC 60601-1-2:2001, an FDA recognized consensus standard for electromagnetic compatibility.
- Line Dropout and Variation Susceptibility were tested according to the FDA Reviewer Guidance for Remarket Notification Submissions, November 1993 Mechanical Shock and Vibration Tests
- Shipping Container Transportation Test

All tests passed the stated criteria.

**Conclusions From Nonclincal Testing**

The testing of the AN6150 Digital Radiology System demonstrates that the performance is substantially equivalent to the predicate devices cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 5 2004

Mr. Donald J. Sherratt
Regulatory Affairs Manager
Analogic Corporation
8 Centennial Drive
PEABODY MA 01960

Re: K040995
Trade/Device Name: AN6150 Digital Radiology System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: 90 KPR
Dated: April 15, 2004
Received: April 26, 2004

Dear Mr. Sherratt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ANALOGIC®

510(k) Number: K040995

Device Name: AN6150 Digital Radiology System

Indications For Use:

The AN6150 is a digital X-ray general radiography system intended for use by qualified/trained doctor or technician and is designed to perform radiographic exposures of the whole body including skull, spinal column, chest, abdomen, extremities and other body parts excluding mammography. Radiographic exposures may be taken with the patient in the sitting, standing, or lying in the prone or supine position.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040995